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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,814	01/30/2001	Olivier Ballevre	112701-136	2493

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,814	BALLEVRE ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-28,32-36,38-41 and 43-55* is/are pending in the application.

4a) Of the above claim(s) *45-49* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-28 and 32-34* is/are rejected.

7)☒ Claim(s) *35-36, 38-41, 43-44 and 50-55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 1-18, 20-28, 32-36, 38-41 and 43-55 are pending

The response filed 5 April 2004, which amends claim 32 has been entered. N0te that claims 19, 29-31, 37 and 42 were cancelled by the applicants' amendment filed 20 October 2003, and that claims 45-49 are withdrawn from consideration by Examiner. Thus, claims 1-18, 20-28, 32-36, 38-41, 43-44 and 50-55 are examined in this Office action.

Claim Rejections under 35 USC §103 is withdrawn because Demichele's patent does not teach that the protein source of the administered nutritional composition comprises at least 5.5% by weight (the limitation set forth in the instant claim 1); and thus, the claim 1 rejection as obvious over Hennebicq-Reig et al. taken with the Demichele's patent and the other cited references falls; and thereby the rejection of the claims that depend from claim 1 is withdrawn.

Provisional Rejection, 35 U.S.C. 101, Double Patenting

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438,

164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 14, 28, 32, 33 and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 14, 28, 32, 33 and 34 of application No.10182854, respectively. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Claim 14 of application 10182854 is word to word identical to claim 14 of the instant application.

The claims of the instant application and claims of the application 10182854 disclose the identical subject matter, *i.e.*, a method of increasing the synthesis of mucins in a patient comprising supplement a diet of the patient by adding threonine to the said diet (see claim 28), and a method of increasing increasing the synthesis of mucins in a patient comprising administering to the patient a composition comprising threonine that is at least 30% of daily recommended amount of threonine (see claims 32-34).

Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d

1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective 1 January 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 20-28 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-18 of Application No.10182854. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 1-18 of instant application have been fully disclosed in their equivalents claims 1-18 of Application No. 10182854, respectively. Claims 1-7 of application 10182854 discloses a method of treating a disease comprising administering a composition to a subject a protein source comprising threonine that is at least 5.5% (w/w) of total *amino acids*. The current application claims 1-7 set forth a method comprising the

same except that threonine comprises 5.5% (w/w) of *protein source*. Because the protein source encompasses amino acids, the claims 1-7 of the current application and application 10182854 are obvious variations. Claims 8-13 of application 10182854 disclose a method of producing a nutritional composition for maintaining the synthesis of mucins in a patient comprising using a protein source comprising threonine that is at least 5.5% (w/w) of the amino acids. Claims 8-13 of the instant application sets forth a method of maintaining the synthesis of mucins in a patient comprising administering to the patient a composition comprising a protein source wherein threonine is at least 5.5% (w/w) of said protein source. Because (i) the claims of instant application and the claims of 10182854 are directed to the common subject matter, i.e., maintaining mucin synthesis, which is inherent in the process of providing or producing threonine-rich composition, and (ii) all the limitations set forth in the dependent claims 9-13 for 10182854 and the current application are identical, the claims of 10182854 and the instant application are obvious variation.

Claims 14-18 of application 10182854 and claims 14-18 of the current application are obvious variation as well. The independent claim 14 for both applications are identical except that 10182854 claim 15 sets forth that threonine comprises at least 5.5% (w/w) of *amino acids* of the protein source in comparison to that the application claim 15 recites that threonine comprises at least 5.5% (w/w) of the *protein source*, wherein the protein source includes milk protein, whey protein and glycoprotein *etc.* (see page 5 of the specification of the instant application). Since the protein source encompasses the amino acids, 10182854 discloses the common subject matter as that of the current application.

Claim 20 of application 10182854 sets forth a method of treating a disease state comprising administering to a patient a nutritional composition that has a protein source comprising threonine which is at least 7.5% (w/w) of amino acids; claim 20 of the instant application disclose the same but threonine amount in the claimed composition is 7.4% (w/w) of the protein source. Since 7.4% is an obvious variation of 7.5%, the claim of 10182854 and the claim of the current application are obvious variation from each other.

Claims 21-23 of the current application and 10182854 are identical except for claim 21 recitation "14% (w/w) of the *protein source*" (the instant application) in comparison with the recitation of claim 21 "14% (w/w) of the *amino acids*" (application 10182854). Since the protein source encompasses the amino acids, application 10182854 discloses the common subject matter of that of the instant application.

Claim 24 of application 10182854 sets forth a method of maintaining mucin synthesis comprising administering to a patient a nutritional composition comprising threonine that is at least 7.4 (w/w) of the acids; claim 20 of the instant application disclose the same but threonine amount in the composition is 7.4% (w/w) of the protein source. Because, in application 10182854, claim 24 is obviously directed to amino acids in view of the specification thereof (see page 5) (herein, amino acids are regarded as species of a genus of biological acid), the claim 24 of the current application and 10182854 are obvious variation.

Claims 25-27 of the current application and 10182854 are identical except for the claim 25 recitation of 10182854 "14% (w/w) of the amino acids" in comparison with the claim 25 recitation of the instant application "14% (w/w) of the *protein source*". Since

the protein source encompasses the amino acids, the claims of these two applications are obvious variation.

Application No. 10182854 claims the same subject matter as the instant application although they are different in scope of the claims compared. Thus, the claims of application 10182854 and the claims of current application are obvious variation.

It is noted that at pages 18-19 of the response filed 5 April 2004 applicants request abeyance of the obvious-type double patenting rejections until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicants timely file the appropriate terminal disclaimer.

Objection to claims

Claims 35-36, 38-41, 43-44 and 50-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Karen Cochrane Carlson PhD

Samuel Wei Liu, Ph.D.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

June 8, 2004